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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,560	02/09/2001	Marianne Harboe	58982.000002	6162

7590 05/19/2009

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EXAMINER	
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ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
05/19/2009	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MARIANNE HARBOE

Appeal 2008-005837
Application 09/779,560
Technology Center 1600

Decided:[1] May 19, 2009

Before ERIC GRIMES, LORA M. GREEN, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of reducing glucoamylase activity in a medium containing recombinantly

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

produced chymosin. The Examiner has rejected the claims for lack of adequate description in the Specification, nonenablement, and obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm all of the rejections.

STATEMENT OF THE CASE

"[M]ilk clotting enzymes, also referred to as rennets or coagulants . . . are widely used in the cheese manufacturing industry" (Spec. 2: 1-3). "The industrially most important milk clotting enzymes of animal origin are chymosin and pepsin" (*id.* at 2: 9-10).

The Specification states that "bovine chymosin is increasingly being manufactured using recombinant DNA technology, e.g. using filamentous fungi such as *Aspergillus* species" (*id.* at 2: 20-21). The Specification states that "currently applied processes for manufacturing of commercial rennet products include steps of recovering the active enzymes from crude extracts or microbial fermentation media, followed by one or more purification steps" (*id.* at 3: 1-3).

The Specification reports "the surprising discovery that undesired enzymatic activities in polypeptide preparations can be reduced or eliminated by a very simple process step of subjecting the preparation to low pH for an appropriate period of time without any significant concurrent inactivation of the active polypeptide" (*id.* at 3: 30-33).

Claims 5, 6, 9-14, 16-18, 35, 36, 39, 42, and 43 are pending and on appeal. The claims subject to each rejection have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claim 9 is the only independent claim and reads as follows:

Claim 9. A method for reducing the glucoamylase activity in a milk clotting composition comprising the steps of:

(i) providing a medium having a pH of 2.0 or higher that comprises chymosin activity and glucoamylase activity, wherein the medium having a pH of 2.0 or higher is derived from the cultivation of an organism that is selected from the group consisting of a bacterial species, a yeast species and a species of filamentous fungi, wherein the organism comprises a gene for encoding chymosin that is derived from a bovine or *Camelidae* species, and

(ii) subjecting said medium to a pH in the range of 1.0 to 1.8 for a period of time sufficient to inactivate at least 50% of said glucoamylase activity while maintaining at least 75% of said chymosin activity.

The claims stand rejected as follows:

- Claims 5, 6, 9-14, 16-18, 35, 36, 39, 42, and 43 under 35 U.S.C. § 112, first paragraph, for lack of adequate written description in the Specification (Answer 5);
- Claims 5, 6, 9-14, 16-18, 35, 36, 39, 42, and 43 under 35 U.S.C. § 112, first paragraph, for lack of an enabling disclosure in the Specification (Answer 10); and
- Claims 5, 6, 9, 12-14, 16-18, 42, and 43 under 35 U.S.C. § 103(a) as obvious in view of Lawlis[2] and Ward[3] (Answer 17).

WRITTEN DESCRIPTION

Issue

The Examiner has rejected claims 5, 6, 9-14, 16-18, 35, 36, 39, 42, and 43 under 35 U.S.C. § 112, first paragraph, on the basis that the

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[2] Lawlis Jr. et al., U.S. Patent 5,801,034, issued Sept. 1, 1998.
[3] Ward et al., *Improved Production of Chymosin in Aspergillus by Expression as a Glucoamylase-Chymosin Fusion,* 8 BIO/TECHNOLOGY 435-440 (1990).

Specification does not adequately describe the genus of chymosin genes recited in the claims (Answer 5-6). The Examiner interprets the "derived from" language of claim 9 as encompassing "a nucleic acid encoding naturally-occurring bovine and *Camelidae* species chymosin as well as mutant and variant forms thereof" (*id.* at 6). The Examiner finds that the instant Specification discloses only a single example of the recited genus (bovine chymosin), and that the prior art does not describe the genus of *Camelidae* chymosin genes (*id.* at 7). The Examiner concludes that the claims are not supported by an adequate description to show possession of the claimed invention (*id.* at 10).

Appellant contends that "it is improper for the examiner to require additional disclosure related to the specific organisms which might be used with the method of the pending claims. The claims are not directed to recombinant organisms themselves and, as such, do not require the same level of disclosures" as required for claims to recombinant organisms per se (Appeal Br. 6).

The issue with respect to this rejection is: Did the Examiner err in concluding that the Specification's description of bovine chymosin is inadequate to show possession of the claimed method of treating chymosin-containing compositions?

Findings of Fact

1. Claim 9 defines a method of treating a medium "derived from the cultivation of an organism . . . , wherein the organism comprises a gene for encoding chymosin that is derived from a bovine or *Camelidae* species" (claim 9).

2. Claim 9 requires subjecting the chymosin-containing medium to a "pH in the range of 1.0 to 1.8 for a period of time sufficient to inactivate at least 50% of [the] glucoamylase activity while maintaining at least 75% of said chymosin activity" (claim 9).

3. Claim 9 therefore recites a genus of chymosin genes having two properties: (i) they are derived from a bovine or *Camelidae* species, and (ii) they encode a chymosin enzyme that retains at least 75% activity after treatment at pH 1.0 to 1.8 has inactivated 50% of the glucoamylase activity in the medium.

4. The Specification states that the disclosed method is applicable to "preparations of aspartic proteases derived from a naturally produced aspartic protease by the addition or deletion of one or more amino acids or substituting one or more amino acids [t]herein" (Spec. 8: 32-35).

5. The Specification's Example 1 and Example 2 describe low-pH treatment of culture medium of "a recombinant strain of *Aspergillus niger* var. *awamori* expressing a prochymosin-glucoamylase fusion protein" (Spec. 9: 24-25; 10: 26-28).

6. The plasmid used in the Specification's Example 1 and Example 2 expressed bovine chymosin (*id.* at 9: 14-15; 10: 17-19).

7. The Specification's Example 3 describes treatment of "commercial microbial and animal rennet products" (*id.* at 15: 6-7).

8. The only animal product included in Example 3 is "CHY-MAX™, a bovine chymosin produced by *Aspergillus niger* var. *awamori*" (*id.* at 15: 12).

9. The Examiner finds that "the genus *Camelidae* . . . encompasses alpaca, llama, vicunas, guanacos, bactrian camel and dromedarian camel" (Answer 6).

10. Appellant's Appeal Brief does not dispute that the genus *Camelidae* encompasses alpacas, llamas, vicuñas, guanacos, bactrian camels and dromedarian camels.

11. The Examiner finds that "the specification and prior art fail to disclose any distinguishing identifying characteristics of a gene encoding a *Camelidae* species chymosin, e.g., the nucleotide sequence of a gene encoding a *Camelidae* species chymosin" (Answer 9).

12. Appellant's Appeal Brief does not dispute the Examiner's finding that the prior art does not disclose the sequence of a chymosin gene from any species in the genus *Camelidae.*

Principles of Law

> Regardless whether a compound is claimed *per se* or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods.

University Of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 926 (Fed. Cir. 2004).

> In claims to genetic material, . . . a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the

> genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function . . . does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997).

A genus of cDNAs can be described "by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* at 1569.

The "written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure'" or a combination thereof. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) (emphasis omitted, alterations in original).

> [W]hat is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.

Capon v. Eshhar, 418 F.3d 1349, 1359 (Fed. Cir. 2005).

Analysis

The Examiner found that the genus of chymosin genes recited in claim 9 lacks adequate description on two grounds: the disclosed species of bovine chymosin is not representative of mutants and variants of chymosin genes that maintain 75% activity at pH 1.0 to 1.8 (Answer 7), and bovine chymosin does not adequately describe the genus of chymosin genes from *Camelidae* species (*id.* at 10). We agree with the reasoning set out by the Examiner in the Answer, and with his finding that the Specification does not adequately describe the method of claim 9.

Appellant does not directly address the Examiner's finding that the Specification discloses only a single chymosin gene encompassed by the genus recited in claim 9 or his finding that this species is not representative of the genus. Appellant argues, instead, that the claims are directed to a method of treating a composition produced by a recombinant organism, not the organism itself, and the Specification adequately describes the claimed method (Appeal Br. 6).

This argument, however, was considered and rejected in *University of Rochester*. The claims in that case were directed to a method of selectively inhibiting the enzyme PGHS-2 (also known as COX-2) by "administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human." 358 F.3d at 918. The patent did not "disclose any compounds that can be used in its claimed methods." *Id.* at 927. The court held that a description of the compound used in the method was required to adequately describe the method. *Id.* at 926.

Similarly here, the claimed method requires using a recombinant bacterium, yeast, or fungus that expresses a chymosin gene derived from a bovine or *Camelidae* species. Just as in *University of Rochester*, an adequate description of the method claimed here requires describing the chymosin genes required to carry out the method.

The facts of this case differ from *University of Rochester* in that the Specification here discloses one species within the recited genus. The court has held, however, that a description of a single species (e.g., rat cDNA encoding insulin) does not necessarily provide adequate description for a genus (e.g., vertebrate or mammalian cDNA encoding insulin). *See Eli Lilly*, 119 F.3d at 1567. A chemical genus may be described in various ways, *see id.* at 1568, *Enzo*, 323 F.3d at 964, but to satisfy the first paragraph of 35 U.S.C. § 112, the description must allow those skilled in the art to "visualize or recognize the identity of the members of the genus." *Eli Lilly*, 119 F.3d at 1568.

Appellant has pointed to no evidence of record that would support a finding that the Specification's description of a bovine chymosin gene is adequate to show possession of the genus of chymosin genes recited in claim 9 and required to practice the claimed method.

Conclusion of law

The Examiner did not err in concluding that the Specification's description of bovine chymosin is inadequate to show possession of the claimed method of treating chymosin-containing compositions.

ENABLEMENT

Issue

The Examiner has rejected claims 5, 6, 9-14, 16-18, 35, 36, 39, 42, and 43 under 35 U.S.C. § 112, first paragraph, on the basis that the Specification is enabling for a method of treating a medium containing bovine chymosin and *Aspergillus niger* glucoamylase, but not for the full scope of the claims (Answer 10). The Examiner concludes that undue experimentation would be required to practice the claimed method using compositions containing chymosins from the various *Camelidae* species and with mutants and variants "derived from" the naturally occurring chymosin genes (*id.* at 12-15).

Appellant contends that the "claims are not directed to recombinant organisms themselves and as such do not require the same level of disclosure that would be required had the claims been directed to broad claims to the organisms themselves." (Appeal Br. 8-9.) Appellant contends that the claims are directed to a method of treating chymosin-containing compositions, the steps of the recited method are adequately enabled, and "it is improper for the examiner to require additional disclosure related to the specific organisms which might be used with the method of the pending claims" (*id.* at 8).

The issue with respect to this rejection is: Did the Examiner err in considering the scope of chymosin genes recited in the claims as a factor in the enablement analysis?

Principles of Law

"[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

> Factors to be considered in determining whether a disclosure would require undue experimentation . . . include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

Analysis

The Examiner has interpreted claim 9 as encompassing a method of treating media comprising mutants and variants of naturally occurring chymosin genes that maintain 75% activity at pH 1.0 to 1.8 and chymosin genes from various *Camelidae* species (Answer 12). We agree with the Examiner's interpretation of the claims, and Appellant does not take issue with it.

Appellant argues, instead, that the claims are directed to a method of treating a composition, not to the materials that are used to make the starting composition. Appellant contends that "there is no need to actually make every possible starting material in order to practice the invention as the specification teaches that the simple steps of the invention may be applied to

chymosin compositions having undesired enzymatic activity" (Appeal Br. 7-8).

Appellant has pointed to no case law supporting her position that the experimentation required to make the starting materials of a claimed method should not be considered in determining whether the method is enabled. The court's analysis in *Wands*, in fact, supports the opposite conclusion.

The claims at issue in *Wands* were directed to an immunoassay method for detecting hepatitis B surface antigen (HbsAg). *Wands*, 858 F.2d at 734. The claimed method required using "a monoclonal high affinity IgM antibody having a binding affinity constant for said HbsAg determinants of at least 10^9 M^{-1}." *Id.* The rejection on appeal was "directed solely to whether the specification enables one skilled in the art to make the monoclonal antibodies that are needed to practice the invention." *Id.* at 735.

The applicants in *Wands* had deposited a single hybridoma expressing antibodies meeting the claim limitations, *id.* at 734, and the applicants' "disclosure provide[d] considerable direction and guidance on how to practice their invention and present[ed] working examples. There was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known." *Id.* at 740. The court held that "Wands' evidence thus effectively rebut[ted] the examiner's challenge to the enablement of their disclosure." *Id.*

This case is similar to *Wands* in that the rejection is based on the Examiner's conclusion that undue experimentation would be required to make the starting materials used in claimed process. *Wands,* therefore supports the basis of the Examiner's rejection.

This case differs from *Wands*, however, in that Appellant has pointed to no evidence in the record to show that obtaining the other chymosin genes encompassed by the claims – chymosin genes from animals of the genus *Camelidae* and mutants or variants of bovine and *Camelidae* chymosin genes – would have required no more than routine experimentation at the time this application was filed.

The Examiner has provided a reasoned analysis, based on the evidence of record and the factors set out in *In re Wands*, for concluding that practicing the full scope of the claimed method would have required undue experimentation at the time of filing. Appellant has not pointed to evidence of record that rebuts the Examiner's challenge to the enablement of the instant disclosure.

Conclusion of law

The Examiner did not err in considering the scope of chymosin genes recited in the claims as a factor in the enablement analysis.

OBVIOUSNESS

Issue

The Examiner has rejected claims 5, 6, 9, 12-14, 16-18, 42, and 43 under 35 U.S.C. § 103(a) based on Lawlis and Ward (Answer 17). The Examiner finds that Lawlis teaches a method of killing cells in culture medium using, for example, formic acid and a pH of 1.75 or less (*id.* at 18), and that Ward teaches *Aspergillus niger* var. *awamori* cells expressing a glucoamylase/chymosin fusion protein (*id.* at 19). The Examiner concludes that it would have been obvious "to use a culture of the transformant of

Ward in a method of Lawlis, namely, treating the culture with sulfuric acid to a pH of 1.75 and then adding formic acid to effect substantial cell kill" (*id.* at 19-20).

Appellant contends that the references do not disclose inactivating at least 50% of glucoamylase activity while maintaining chymosin activity, and that this property is not inherent in Lawlis' method because Lawlis' preferred embodiment of acetic acid would not require using a pH of 1.0 to 1.8 (Appeal Br. 10-11). Appellant also contends that inactivating glucoamylase activity without destroying the chymosin activity is an unexpected result of low pH treatment (*id.* at 13).

The issue with respect to this rejection is: Does the evidence of record, considered as a whole, support the Examiner's conclusion that it would have been obvious to those of ordinary skill in the art to subject Ward's chymosin-containing medium to a pH of 1.75, as taught by Lawlis?

Additional Findings of Fact

13. Ward discloses an expression vector encoding bovine prochymosin B fused in frame with the glucoamylase (*glaA*) gene of *Aspergillus niger* var. *awamori*, or *A. awamori* (Ward 435).

14. Ward discloses that "this plasmid led to the secretion of considerably higher amounts of chymosin than obtained with previous chymosin expression vectors" (*id.* at 435, right col.).

15. Ward discloses that the evidence "suggests that mature chymosin is autocatalytically released from the glucoamylase-chymosin fusion protein after secretion" (*id.*).

16. Ward discloses that "an increase in active chymosin concentration could be induced simply by lowering the pH of samples to 2" (*id.* at 439, right col.).

17. Lawlis discloses that it is necessary to kill microorganisms expressing recombinant DNA at the end of a fermentation process in order to prevent release of recombinant organisms into the environment (Lawlis, col. 1, ll. 18-25).

18. Lawlis discloses that

> it is desirable to simply kill the microorganisms without lysing the cells . . . in systems where the cells manufacture and secrete the desired product extracellularly because lysing the cells releases additional cell debris and materials into the medium, thus making recovery and purification of the desired secreted product more difficult and costly.

(*Id.* at col. 1, ll. 46-52.)

19. Lawlis discloses that "in a culture of *Aspergillus niger* for the production of chymosin, reducing the pH to about 2 using sulfuric acid does not accomplish a complete or substantially complete cell kill" (*id.* at col. 2, ll. 61-64).

20. Lawlis discloses a method of killing yeast, bacteria, or fungi in a culture by

> selecting a compatible organic acid having 1 to 5 carbon atoms or a compatible salt thereof, and then in either order;
>
> (i) adjusting the pH of the culture to a value equal to or less than about 2 pH units below the pK_a of the selected compatible organic acid and/or salt thereof; and
>
> (ii) adding a sufficient amount of the selected compatible organic acid and/or salt

> to effect a substantially complete kill of the microorganism in the culture.

(*Id.* at col. 2, ll. 28-39.)

21. Lawlis discloses that the "'organic acid' employed . . . can be any suitable and compatible acid having 1 to about 5 carbon atoms" (*id.* at col. 3, ll. 29-31).

22. Lawlis discloses that a "preferred acid is acetic acid because it is effective with a wide range of cells and because it is one of the lowest cost acids available. Other effective acids can be used depending on the cell cultures involved and the economics of the process." (*Id.* at col. 4, ll. 49-53.)

23. Lawlis discloses that, "[f]or example, if formic acid (pK_a=3.75) is to be used to accomplish the cell kill, the pH of the mixture will be adjusted with a mineral acid to about 1.75 or less, then formic acid is added to accomplish the cell kill" (*id.* at col. 3, ll. 56-60).

24. Lawlis provides a working example describing "a substantially complete cell kill of *A. niger var. awamori*" by adjusting the pH to 2.0 with sulfuric acid and addition of 4% glacial acetic acid, followed by storage overnight (*id.* at col. 6, ll. 4-29).

25. The instant Specification discloses that the

> low pH treatment according to the invention is made for a period of time that is required to inactivate the side activity/activities to a desired level and that does not inactivate the biological activity of the desired polypeptide unacceptably. Typically, however, the required treatment period is within the range of 0.1 minutes to 48 hours such as a range of 1 minute to 36 hours including the range of 10 minutes to 24 hours.

(Spec. 7: 19-22.)

Principles of Law

> An invention
>
> composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. . . . [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418 (2007).

> In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. . . . [A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

Id. at 419-20.

> In some cases, [an] inherent property corresponds to a claimed new benefit or characteristic of an invention otherwise in the prior art. In those cases, the new realization alone does not render the old invention patentable. . . . Thus, when considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure.

Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1377-1378 (Fed. Cir. 2005).

"[I]t is well settled that unexpected results must be established by factual evidence. 'Mere argument or conclusory statements in the specification does not suffice.'" *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997), quoting *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984).

Analysis

Ward discloses recombinant *A. niger* var. *awamori* cells that secrete a glucoamylase/bovine chymosin fusion protein into the culture medium. Ward teaches that active chymosin is released from the fusion protein, probably through autocatalytic cleavage, and that lowering the pH to 2 increases the amount of active chymosin.

Lawlis teaches that killing recombinant cultured cells without lysing the cells is useful where the cells secrete the desired protein into the culture medium. Lawlis teaches a method for killing cells without lysing them by lowering the pH of the medium to at least 2 pH units below the pK_a of an organic acid having 1-5 carbon atoms. Lawlis expressly suggests using formic acid and lowering the pH of the medium to 1.75 or lower.

It would have been obvious to a person of ordinary skill in the art to use Lawlis' method of cell-killing to kill the chymosin-expressing cells taught by Ward because Ward's cells secrete the desired chymosin into the culture medium, and Lawlis discloses that its method of killing cells without lysing them is especially useful for such cells. A person of ordinary skill in the art also would have considered it obvious to use a combination of formic acid and a pH of 1.75 or lower in Lawlis' method because Lawlis expressly suggests that combination.

A skilled worker would have reasonably expected that Lawlis' method would not adversely affect the activity of the chymosin produced by Ward's cells because Ward teaches that a pH of 2 actually increased the amount of active chymosin, and pH 1.75 is reasonably close to pH 2. Neither Lawlis nor Ward discuss the effect of low pH on glucoamylase, but

Lawlis exemplifies acid treatment carried out overnight, and the instant Specification states that acid treatment for as little as 0.1 minutes is enough to inactivate side activities such as glucoamylase. Therefore, it is reasonable to conclude that combining Lawlis' method with Ward's cells would inherently result in inactivating at least 50% of glucoamylase activity.

Appellant argues that the references do not suggest inactivating glucoamylase activity by reducing pH, or that "this can be accomplished without destroying the chymosin activity" (Appeal Br. 13). Appellant argues that the Examiner's conclusion that the method suggested by the prior art would have inherently caused these effects is improper because "there is no showing that the unexpected results would have been recognized or appreciated by a person having ordinary skill in the art" (*id.*).

This argument is not persuasive. The references do not suggest treating bovine chymosin-containing culture medium to low pH in order to inactivate glucoamylase, but the prior art need not suggest combining teachings for the same reason the applicant combined them in order to make a claimed invention obvious. Here, a skilled artisan would have combined Lawlis' low pH treatment with Ward's culture in order to kill the cells in Ward's culture without lysing them. The effect of inactivating 50% of the glucoamylase activity, as recited in the instant claims, is simply an inherent result of practicing the method made obvious by the prior art.

In addition, Appellant has pointed to no evidence of record to support her argument that the effect of low pH on glucoamylase activity would not have been expected by those of skill in the art. An assertion of unexpected results must be supported by evidence, not just attorney argument or

conclusory statements. Since no evidence has been cited, Appellant's argument based on unexpected results is not persuasive.

Conclusion of law

The evidence of record, considered as a whole, supports the Examiner's conclusion that it would have been obvious to those of ordinary skill in the art to subject Ward's chymosin-containing medium to a pH of 1.75, as taught by Lawlis.

SUMMARY

We affirm the rejection of claims 5, 6, 9-14, 16-18, 35, 36, 39, 42, and 43 under 35 U.S.C. § 112, first paragraph, for both lack of enablement and lack of adequate written description in the Specification. We affirm the rejection of claims 5, 6, 9, 12-14, 16-18, 42, and 43 under 35 U.S.C. § 103(a) as obvious in view of Lawlis and Ward.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

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